SURGICAL-IMAGE LABORATORIES, INC.

JUN 1 2 2000

1239 E. Newport Center Dr. Suite 117 . Deerfield Beach, FL 33442 . (800) 917-2673 . Tel: (954) 480-8323 . Fax: (954) 480-8376

Tab 7
Premarket Notification [510(k)] Summary

K001594

Date May 15, 2000

Trade Name: 3.5mm Laparoscope (LG100, LG103)

Common Name: Laparoscope

Classification Name: Laparoscope, General & Plastic Surgery, SU GCJ (per 21CFR section 876. 1500)

Manufacturer's Name: Surgical Image Laboratories, Inc.
Address: 1456 West Newport Center Drive
Deerfield Beach, FL 33442

Corresponding Official: Zoltan Balazs
Title: President

Telephone: 800-917-2673 **Fax:** 954-480-8376

Predicate: Surgical Image Laboratories LL 100, 103, 104 Diagnostic Laparoscope Rigid Rod, K955845

Device Description:

This Surgical Image Laboratories, Inc., laparoscope is virtually identical to the predicate device in appearance, design materials and features. All laparoscopes are comprised of a stainless steel tube which contains fiberoptic components for illumination light transmission and rod lenses for image transmission. The tube is attached to a non-corrosive housing block and a plastic eyepiece onto which may be joined an image coupler or beamsplitter or through which the doctor can view directly.

Intended Use:

A laparoscope is used by a surgeon for viewing an interior cavity of the human body in a endoscopic or laparoscopic surgical procedure. Laparoscopes are utilized by skilled physicians who use them in accordance with procedures and practices taught in medical schools or special medical training courses.

Technological Characteristics

See the attached "Predicate Comparison Table".

Tab 7

Predicate Comparison Table and Summary

FEATURE	SURGICAL IMAGE MODEL# LL 100/LL 103	SURGICAL IMAGE MODEL # LG 100/LG103
510(k)	K955845	Pending
Regulatory Classification	Class II	Class II
Intended Use	General laparoscopic procedures	General laparoscopic procedures
The structural components	Stainless steel 304L plated brass	Stainless steel 304L plated brass
Eyepiece	Anodized aluminium Acetal plastic	Anodized aluminium Acetal plastic
The optical system	Optical glass, adhesives and coatings	Optical glass, adhesives and coatings
Light transmission system	Glass fibers imbedded in adhesives	Glass fibers imbedded in adhesives

FEATURE	LL100/LL103	LG100/LG103
O.D.	10.0mm	3.50mm
Length	420mm	360mm
Working Length	353mm	300mm
Weight	144g	70g
Attachments Trocar	10mm	3.5mm
Attachments fiber optics light cable	Storz, Olympus, Wolf, Circon	Storz, Olympus, Wolf, Circon
Attachements Coupler	Focusable couplers fit scopes to cameras of virtually any make or model 35mm focal lengths	Focusable couplers fit scopes to cameras of virtually any make or model 35mm focal lengths
Lens Diameter	6.0mm	2.70mm
Material	BK7 517642 Optical glass 1.45<N<1.9 Quartz glass	BK7 517642 Optical glass 1.45<N<1.9 Quartz glass
Coating	Multi layer anti-reflection coating visible light wavelegnth range 420nm-670nm	Multi layer anti-reflection coating visible light wavelegnth range 420nm-670nm
Objective lens	0 degree, 30 degree 45 degree	0 degree, 30 degree
Working Distance	25.0mm	25.0mm
MTF Center (at 6.0lp/deg.)	100.2%	94.3%
MTF Average edge	100.7%%	97.4%
MTF Minimum edge	98.7%	90.7%
Vignetting Maximum	-1.2%	3.4%
Transmission	104.5%	8.5%
Blue/Green Ratio	99.8%	94.6%
Red/Green Ratio	99.1%	101.7%

FEATURE	LL100/LL103	LG100/LG103
Real Field of View	70.2 degree	53.7 degree
Apparent Field of View	12.1 degree	7.5 degree
Alignment of Apparent Field	2.4%	0.5%
Distortion Maximum	19.8%	12.9%
Illumination Center Transmission	661.9%	177.1%
illumination Average Edge	17.4%	43.1%
Illumination Minimum Edge	14.5%	32.3%
Exit Pupil Diameter	3.2mm	1.4mm
Exit Pupil Decentration	<0.25mm	<0.25mm
Eye Relief	0.0mm	0.00mm
Image Blemishes	none	none
Direction of light	0 degree/30 degree 45 degree	0 degree/30 degree
Light Fiber Pixels NA-55 LFS /NA-66F2	DIA 0.051mm	DIA 0.051mm
Light Fibers Bundle DIA.	6.0mm	2.0mm
Number of Fibers	9700	3300
Power Rating with 300W Light Source L.1.5m 0.6mm Light Cable	66 watts	66 watts
Sterilization	Autoclavable Sold non-sterile Sterilization by 100% Ethylenx Oxide Freon/Ethylene Oxide Cidex and the Steris	Autoclavable Sold non-sterile Sterilization by 100% Ethylenx Oxide Freon/Ethylene Oxide Cidex and the Steris

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2000

Mr. Zoltan Balazs
President
Surgical Image Laboratories, Inc.
1456 West Newport Center Drive
Deerfield Beach, Florida 33442

Re: K001594
Trade Name: 3.5 mm Laparoscope (LG100, LG103)
Regulatory Class: II
Product Code: GCJ
Dated: May 15, 2000
Received: May 23, 2000

Dear Mr. Balazs:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Tab 6

Indications For Use

510(k) Number (~~if known~~): K001594

Device Name: Laparoscope

Indications For Use:

The Laparoscope is primarily indicated for patients undergoing endoscopic or laparoscopic surgical procedures where use of a rigid Laparoscope is appropriate.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001594

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)